Support Document #65

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM **Date: August 6, 2002**

SUBJECT: EFED's Revised Policy Guidance for Section 18's

FROM: Steven Bradbury, Acting Division Director
Environmental Fate and Effects Division
Office of Pestcide Programs

TO: EFED Staff and Managers

To address the following concerns raised by RD and FEAD, the delivery process and responsibilities listed below should be implemented as of this date. Briefly, the issues are: 1) the need for consistency in content of EFED responses to Section 18's and clarity in risk conclusions; 2) the need to develop risk characterization and mitigation measures when LOCs are exceeded; 3) the need to refine the endangered species list; and 4) the need for EFED/FEAD to identify a person for the users of the Section 18 to contact when there are endangered species concerns.

Delivery Process

1) At least 3 days before submitting the final document to RD (only if an endangered species level of concern has been exceeded), the draft Section 18 document should be submitted to EFED's liaison to the endangered species group (currently Bill Erickson or his designee) and FEAD (Ron Kendall and Barbara Sullivan) electronically for review and comment.

2)) The final Section 18 response must be sent electronically to the EFED tracking team, Section 18 reviewer, FEAD, and the RD PM. A hard copy must also be sent to the RD Section 18 reviewer.

Responsibilities

RD

- On the BEAN sheets, the RD Section 18 Team will clearly identify the package content and EFED's needed action. For example, a) does the state want to see specific mitigation measures considered; b) has the state indicated if endangered species are or are not going to be

affected; c) if the Section 18 is a recurrent request specify on the BEAN sheet what is requested of EFED; d) indicate if the Section 18 went crisis and provide a specific date for EFED's response; e) indicate if a Section 18 has recently been submitted for the same crop but in a different state.

EFED

- EFED will follow the guidance for Section 18 responses (**see attached**). If the response to a Section 18 request is the same as one that EFED has already submitted, a new Section 18 review is not required. A short note referencing the previous assessment and a copy of the document will suffice. Endangered species issues, however, need to be considered in the new response.

- If EFED is in the process of conducting an assessment for a Section 3 or reregistration action for the pesticide, and risk characterization and risk mitigation information is prepared, EFED will include this information in the Section 18, if time permits.

- EFED will include in the Section 18 a county-level endangered species list of organisms that exceed the endangered species LOC. In addition, where information is readily available, and time permitting, EFED will provide a more refined endangered species list and risk characterization of specific endangered species on the list. The EFED/FEAD liaison can assist in this effort.

FEAD

- Once EFED has completed its phase of the endangered species assessment, the endangered species team in FEAD will, as time permits, provide a more refined endangered species list and any further risk characterization and mitigation measures that are readily identifiable. FEAD will contact RD and EFED if significant issues are identified.

- If the LOC has been exceeded for endangered species, the endangered species team in FEAD will provide, if available, information regarding the appropriate person that the section 18 user(s) should contact.

- FEAD will provide any specific language necessary to appropriately characterize the Endangered Species Program.

If you have any questions please contact Jean Holmes (703-605-0211).

cc: Robert Forest, Chief
Emergency Response Branch
Registration Division

Arty Williams, Chief
Environmental Field Branch
Field and External Affairs Division

EFED Policy Guidance for Documenting Section 18s Assessments

I. Summary of Conclusions

A bottom line conclusion for the Section 18.

- If there are risks associated with a particular use, identify which levels of concern have been exceeded. (See attached list of terrestrial, aquatic, and plant levels of concern.)
- Indicate if there are endangered species concern triggered in the use area (list later in document).
- Indicate if there is a ground water or surface water contamination concern.
- Recommended drinking water concentrations for HED
- EFED label recommendations (not the ones currently on the label)

II. Background

Submission purpose and requested use.

- Indicate the registration #, trade name, pesticide type, and formulation type of the pesticide.
- Indicate the requested section 18 use pattern (e.g. use pattern, including application type/equipment, maximum application rate, crop, etc.).

III. Environmental Fate Summary

Very brief summary of the environmental fate including uncertainties.

- Identify the major route(s) of dissipation.
- Brief assessment of the persistence of parent and the formation and decline of major degradates.
- Brief assessment of mobility of parent and major degradates.

IV. Water Resource Summary

A. Surface Water (modeling and monitoring)

1) Ecological exposure

GENEEC II model, or PRZM/EXAMS (if available in the files and not conducted prior to 1996).

- Provide input parameters with associated values (include units), and results.
- Modeling is not required if visual inspection of the relevant information (ecological toxicity data, use rates, and drinking water model results) allows for a qualitative conclusion that risk for a given organism group (i.e. fish aquatic invertebrates) is minimal.

2) Drinking water

FIRST model, or PRZM/EXAMS (if run for chemical at maximum exposure is available in the files and not conducted prior to 1996).

3) Monitoring

Include monitoring data if it has been previously evaluated, has been used in a previous exposure assessment, and will help in the decision for the Section 18. If monitoring data is included:

- State the source of the monitoring data (ex. NAWQA), monitoring values and brief description of quality of the data.
- Indicate the location of the monitoring data (eg., regions, states)

B. Ground Water (modeling and monitoring)

- For the SCI-GROW model, provide input parameters, input values, and results.
- Include monitoring data if it has been previously evaluated and has been used in place of modeling. If included, identify the source of the monitoring data (ex. NAWQA, Pesticides in Ground Water Data Base) and monitoring values, as well as the location of the monitoring data (ex. regions, states). Also provide a brief description of quality of the data.

C. Drinking Water Concentrations Recommendation.

- EFED's estimated drinking water concentration for HED.
- Include the Maximum Contaminant Level (MCL) and Health Advisory (HA) numbers if available.

V. Aquatic Organisms Risk Assessment

Brief description of aquatic hazard and risk, including uncertainties in the assessment.

- Provide a toxicity summary indicating the most sensitive freshwater fish, freshwater invertebrate, aquatic plants, and where applicable, amphibian, estuarine and marine species.
- If the toxicity data are included in the risk quotient table (Section VII) and the species is identified with the footnote for each toxicity data point, there is no reason to restate toxicity endpoints (LC50, EC50, etc.) in this section.

VI. Terrestrial Animal Risk Assessment

Brief description of terrestrial hazard and risk, including uncertainties in the assessment.

- Provide a toxicity summary indicating the most sensitive mammalian, terrestrial plant, and avian species.
- If the toxicity data are included in the risk quotient table (Section VII) and the species is identified with the footnote for each toxicity data point, there is no reason to restate toxicity endpoints (LC50, EC50, etc.) in this section.
- Results of mammalian studies do not always have to be included in the section 18; however, when avian risk is used to represent mammalian risk make this clear in the document. If there is a previous review in the file with a mammalian risk assessment, include a brief summary of this in the section 18 and reference the other review.
- With regard to the terrestrial plant risk assessment, when the section18 is for a herbicide and phytotoxicity data are available in the files, the list of crops tested should be provided but not the

values of the test results. This will let RD know that phytotoxicity data are available in the event that the crops that have been tested are in the vicinity of the crop to be treated.

VII. Risk Quotient Table

Provide a table of risk quotients for most sensitive species of each of the organisms described above. Include the LD50s, LC50s, EC50s, EC25s, chronic NOAEC, and MRID #s of each study. (Example attached)
- A table of risk quotients is not required if it is more efficient and clear to provide a discussion of the risks in sections V and VI,

VIII. Endangered Species

- Provide a list of endangered species in the affected counties for which the level of concern has been exceeded.
- The reviewer should exclude species from the list not likely to be exposed due to their habitat requirements or natural history.
- If the state has provided a discussion on how they plan to address endangered species concerns, and this discussion causes us to change our conclusions, include the state's information in the section 18.

IX. Recommended Label Restrictions (if needed)

- Provide additional EFED recommendations (do not list ones currently on the label).

X. References (if needed)

- If there has been contact with the state related to this Section 18 request, indicate in this section who was contacted.

List of Items Not to Include in Section 18 Responses

1) Do not need Risk Quotients in the summary.

2) Do not need status of data requirements.

3) Do not include the list of EFED's terrestrial, aquatic, and plant levels of concerns. (That list is attached to the Section 18 response guidance document).

4) Do not include a list of all studies or study details unless directly pertinent to the Section 18 request. For example, if the most sensitive freshwater fish is rainbow trout, do not list all the freshwater aquatic organisms. Also, do not include a detailed explanation of fate studies.

5) Do not list all the endangered species in the Section 18. Provide only a list of endangered species in the Section 18 request area for which the level of concern has been exceeded.

Theoretical Example of Risk Quotient Table

Risk Quotients for Cole Crops/Leafy Vegetables
Ground Foliar Spray; 6 Applications at 0.015 lbs ai/A

(Terrestrial EEC's Based on Fletcher's Residue and Fate Model; Terrestrial Plant Exposure based on "back of the envelope"; Aquatic EEC's Based on PRZM/EXAMS Model)

Surrogate Species		Exposure	Toxicity	Risk Quotient
Mammalian Herbivores LD_{50}[a]	(15 g bw)		23 ppm	0.13 - 0.24
	(35 g bw)		33 ppm	0.092 - 0.16
	(1000 g bw)	3.05[1] - 5.43[2] ppm	147 ppm	0.021 - 0.037
Mammalian Insectivores LD_{50}[a]	(15 g bw)		23 ppm	0.01 - 0.13
	(35 g bw)		33 ppm	0.01 - 0.092
	(1000 g bw)	0.34[3] - 3.05[4] ppm	147 ppm	0.002 - 0.021
Mammalian Granivores LD_{50}[a]	(15 g bw)		140 ppm	0.002
	(35 g bw)		147 ppm	0.002
	(1000 g bw)	0.34[5] ppm	733 ppm	0.0005
Mammalian Reproduction NOEL[b]		0.34 - 5.43 ppm	12 ppm	0.028--0.45
Avian Subacute Dietary LC_{50}[c]		0.34 - 5.43 ppm	570 ppm	0.0006 - 0.01
Avian Reproduction NOEL[d]		0.34 - 5.43 ppm	40 ppm	0.009 - 0.14
Freshwater Fish Acute LC_{50}[e]		0.107[6] ppb	174 ppb	0.00061
Fish Reproduction NOEC[f]		.024[7] ppb	12 ppb	0.002
Aquatic Invertebrate Acute LC_{50}[g]		0.107 ppb	1 ppb	0.11
Freshwater Invertebrate Reproduction NOEC[h]		.024[8] ppb	0.088 ppb	0.27
Estuarine Fish Acute LC_{50}[i]		0.107 ppb	1,430 ppb	0.000075
Estuarine Invertebrate LC_{50}[j]		0.107 ppb	0.04 ppb	2.68
Estuarine Invertebrate Reproduction NOEC[k]		.024 ppb	0.018[9] ppb	1.33
Corn (*Zea maize*) EC25[l]		0.5 lb ai/A	0.01[10] lb ai/A	0.02
Selenastrum capricornatum EC_{50}[m]		0.107 ppb	> 3.9 ppb	<0.027
Duck Weed (*Lemna gibba* G3) EC50[m]		0.107 ppb	> 94 ppb	<0.0011

Footnotes:
a MRID # 00123456 (identify species)
b MRID # 00123457 (identify species)

c MRID # 00123458 (identify species)
e MRID # 00123459 (identify species)
f MRID # 00123457 (identify species)
g MRID # 00123458 (identify species)
h MRID # 00123459 (identify species)

i MRID # 00123466 (identify species)
j MRID # 00123467 (identify species)
k MRID #00123500 (identify species)
l MRID # 00123512 (identify species)
m MRID # 0012513 (identify species)

[1] Residue levels on small insects and forage (135 ppm/lb ai/A)
[2] Residue levels on short grass (240 ppm/lb ai/A)
[3] Residue levels on large insects (15 ppm/lb ai/A)
[4] Residue levels on small insects (135 ppm/lb ai/A)
[5] Residue levels on seeds (15 ppm/lb ai/A)
[6] Peak water concentration
[7] Average 60-day water concentration
[8] Average 21-day water concentration (note ave. 21-day =ave 60-day)
[9] Mysid shrimp reproduction study not validated
[10] Total loading to a smi-aquatic area